

**\* 811. Misbranding of Brown's Nosopen. U. S. v. 12 Cartons of Brown's Nosopen. Default decree of condemnation and destruction. (F. D. C. No. 7640. Sample No. 83803-E.)**

On June 16, 1942, the United States attorney for the Southern District of Texas filed a libel against 12 cartons of Brown's Nosopen at Houston, Tex., alleging that the article had been shipped in interstate commerce on or about January 7, 1942, from Lawton, Okla., by the Am-Bro Co.

Examination showed that the article contained 2 units designated "No. 1 Solution" and "No. 2 Solution," respectively. Analyses of samples showed that the No. 1 solution consisted essentially of ephedrine sulfate (approximately 1 percent), chlorobutanol, and water; and that the No. 2 solution consisted essentially of ephedrine alkaloid (approximately  $\frac{3}{4}$  percent), and small proportions of volatile oils including camphor, menthol, and oil of eucalyptus in a mineral oil base.

The article was alleged to be misbranded (1) in that both solutions contained ephedrine but the labeling failed to warn that frequent or continued use might cause nervousness, restlessness, and sleeplessness and that it should not be used by individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble except upon competent advice, and in that the No. 2 solution contained mineral oil and its labeling failed to warn frequent or excessive use might cause injury to the lungs and that it should not be given to infants and younger children except on competent advice; (2) in that its name, "Nosopen," was false and misleading since it represented and suggested that it would open the nasal passages and make breathing easier, whereas it would not accomplish such results; and (3) in that a statement on the label, "Discomforts of Hay-Fever, Asthma, Sinus-Head-Colds," was false and misleading since it represented and suggested that the article would be efficacious for all discomforts of the conditions described, whereas it would be effective only to lessen nasal congestion.

On July 31, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**812. Misbranding of Texas Crystals. U. S. v. 47 Packages of Texas Crystals. Default decree of condemnation and destruction. (F. D. C. No. 7585. Sample No. 78303-E.)**

In addition to failure to bear such warnings as are necessary for the protection of users, the labeling of this product failed to declare that sodium sulfate was the only ingredient present in an appreciable amount.

On May 29, 1942, the United States attorney for the District of Maryland filed a libel against 47 packages of Texas Crystals at Baltimore, Md., alleging that the article had been shipped in interstate commerce on or about April 8 and May 1, 1942, by Loye Distributing Co. from Fairmont, W. Va.

Analysis of a sample of the article showed that it consisted of hydrated sodium sulfate with traces of other inorganic salts.

The article was alleged to be misbranded (1) in that it was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives; (2) in that the statement appearing on the label, "Analysis sodium sulphate, calcium carbonate, sodium chloride, magnesium carbonate, potassium chloride, sodium carbonate, traces of iron and aluminum oxide," was misleading since it failed to reveal the fact that the article did not contain appreciable amounts of any ingredient except sodium sulfate.

On July 21, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**813. Misbranding of Purola Female Pills. U. S. v. 44 Packages of Purola Female Pills. Default decree of condemnation and destruction. (F. D. C. No. 6864. Sample No. 93031-E.)**

On February 18, 1942, the United States attorney for the Western District of Washington filed a libel against 44 packages of Purola Female Pills at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about November 19, 1941, by McKesson & Robbins, Inc., from Portland, Oreg. The article was labeled in part: "Purola Female Pills \* \* \* Packed for Blumauer-Frank Drug Co. Portland, Oregon."

Analysis showed that the article consisted essentially of laxative plant drugs including aloes, oil of tansy, alkaloidal material, probably derived from ergot, and iron sulfate.

It was alleged to be misbranded (1) in that it was a laxative when used as directed, but its labeling failed to bear warnings that it should not be used

when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence upon laxative; (2) in that the statements (carton) "Female Pills" and (slip in box) "Take one pill three times daily for four or five days previous to expected period," were false and misleading since they created the impression that it would be effective in promoting the menstrual flow, whereas it would not be so effective.

On July 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**814. Misbranding of Stevens Concentrated Mineral Water. U. S. v. 67 Bottles of Stevens Concentrated Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 7522. Sample 87789-E.)**

On May 15, 1942, the United States attorney for the District of Columbia filed a libel against the above-named product at Washington, D. C., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by E. A. Stevens, from Dawson Springs, Ky.

Analysis of a sample of the article showed that it consisted essentially of water, magnesium sulfate, calcium sulfate and small proportions of sodium sulfate, sodium chloride, calcium carbonate, and potassium chloride.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since it was a laxative and the directions provided for continuous administration, whereas a laxative should not be used continuously; (2) in that its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and failed to warn that its frequent or continued use might result in dependence upon a laxative; and (3) in that statements in the labeling which represented and suggested that it had given remarkable results for years in many of the ailments of the human system, was efficacious as a regulator and would be efficacious to maintain and restore health, would be efficacious in the treatment of liver, kidney, and stomach trouble, dropsical trouble, rheumatism, malaria, and poor appetite, loss of weight, nervousness, headaches, gas on the stomach, sleeplessness, pains in the legs and a generally depressed condition of the spirits, stomach trouble, constipation, pains in the side, gall-bladder trouble, dead liver, chronic gastric, prostrated gland suffering, flu, run-down condition, acute and chronic nephritis, bedema, dyspnoea and anasarca with indications for the elimination of both fluids and toxins to prevent uremia, engorged condition of the liver or kidneys, gout or any of the uric acid diatheses, bilious conditions, jaundice, intestinal derangements, anemias chlorosis, all blood and constitutional diseases, sluggish portal circulation, coated tongue, and sallow complexion, were false and misleading since the article would not be efficacious for such purposes.

On June 29, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\***

**815. Adulteration and misbranding of milk of magnesia. U. S. v. Certified Pharmacal Co., Inc. Plea of guilty. Fine, \$40. (F. D. C. No. 6461. Sample No. 53412-E.)**

On June 30, 1942, the United States attorney for the Southern District of New York filed an information against the Certified Pharmacal Co., Inc., New York, N. Y., alleging shipment on or about December 9, 1940, and June 19, 1941, from the State of New York into the State of California, of quantities of milk of magnesia which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from and its quality fell below the standard set forth therein, since samples taken from each of the two shipments showed the presence of 5.85 percent and 5.93 percent of magnesium hydroxide respectively, and its difference in strength and quality from the standard was not plainly stated on its label. The United States Pharmacopoeia provides that milk of magnesia shall contain not less than 7 percent of magnesium hydroxide.

It was alleged to be misbranded in that the label statements "Milk of Magnesia

\* See also Nos. 805, 806, 807.